UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	)	MDL No. 1456
	)	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	)	Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM REGARDING THE BERNDT REPORT

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I. INTRODUCTION

In order for it to be useful, Dr. Berndt's report has to be evaluated in the context of the standards governing a class certification motion. Such standards require that plaintiffs make a "showing" of how legal and factual issues can be presented on a class-wide basis. Plaintiff may do so, in part, through the use of expert testimony that must be "not so flawed as to be inadmissible."

When these standards are properly applied, Dr. Berndt's "initial observations" support plaintiffs' motion for class certification. First, as to the Part B Class, Dr. Berndt confirms that AWP was the "de facto" reimbursement benchmark. And he confirms in unequivocal terms that generic drug manufacturers were using the spread to market their drugs. Defendants had contested both of these points with respect to certification of the Part B Class.

Second, as to the non-Part B aspect of the physician-administered Class, Dr. Berndt finds the record is to "unsettled" for him to conclude that AWP is the basis for reimbursement. However, by limiting the Class to those whose contracts expressly reply on AWP, plaintiffs have solved this problem. Further, to the extent the record is unsettled, such a state arises solely from Young's sur-reply materials. Plaintiffs' motion to strike Young's declaration, which is based on a shockingly misleading presentation, settles the record. As to other aspects of this Class, Dr. Berndt does agree that in this market physicians have an incentive to and can take advantage of the spread between AWP and their acquisition price, and that the system invites "abuse" of the spread. He thus agrees with the common issues as to this Class.

Third, as to the self-administered Class, Dr. Berndt agrees with Dr. Hartman that AWP is the industry standard used for reimbursement and that the market expected a reasonable relationship to exist between AWP, WAC, and ASP. Defendants, largely through Young, vigorously contested the existence of this core common issue.

Fourth, as to perhaps the most contentious issue on the class motion, Dr. Hartman's use of "yardsticks" that set a standard based on market expectations as to the relationship between AWP and ASP, Dr. Berndt does not find this an implausible method of proceeding. Although Dr. Berndt offers suggestions as to how Dr. Hartman's model might be refined, and identifies factors which he believes must be considered in finalizing yardsticks, such refinements often occur, and will occur in this case, between the time the motion for class certification was filed and the filing of final liability and damage reports.

II. THE CONTEXT BY WHICH DR. BERNDT'S OPINION SHOULD BE CONSIDERED

Plaintiffs submit that Dr. Berndt's report must be considered in the context of the legal standards governing class certification. In this regard, there is no serious dispute that at this stage of the proceeding merits determinations are not appropriate. *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 298 (1st Cir. 2000). Dr. Berndt admits at the outside that he "crossed that line" and has in fact offered opinions on the merits.[1] As explained below he has repeatedly offered opinions on the merits, a problem compounded by the fact he has had time to make only what he calls "initial observations." *Id.* at ¶ 234.

Further, there is little dispute that the role of the Court at this stage is to examine the issues to see if proofs are "susceptible to common proof." 208 F.3d at 298. As to experts, the Court may not weigh conflicting expert testimony; instead, the Court is to ensure that plaintiffs' expert's opinion "is not so flawed as to be inadmissible" and that plaintiffs have made "some showing" that the requirements of Rule 23 have been satisfied.[2]

With these standards in mind, Dr. Berndt's report should be assessed concerning its usefulness in assisting the Court as to whether (1) the issues are "susceptible to common proof";

[1] Report of Independent Expert Professor Ernst R. Berndt ("Berndt"), ¶ 9.

[2] *See, e.g., In re Initial Pub. Offering Sec. Litig.*, 2004 U.S. Dist. Lexis 20497, at *84 (S.D.N.Y. Oct. 13, 2004).

(2) have plaintiffs made "some showing," of an ability to muster common proof; and (3) is that showing based in part on an opinion that "is not so flawed as to be inadmissible."

Dr. Berndt's report, when carefully stripped of his admitted opinions on the merits, and lengthy discussions regarding PBM's and competition (which is perhaps marginally relevant to the merits and certainly not to class issues), actually confirms many of the common practices that are cited by Dr. Hartman and which provide the basis for his methodology and plaintiffs class-wide proof. And, though Dr. Berndt offers criticisms of Dr. Hartman's methodologies, he does not opine that these methodologies are not plausible, or are outside the scope of recognized economic analysis. Dr. Berndt does not opine that plaintiffs have not made "a showing."

Finally, as a preliminary matter, before turning to the common issues confirmed by Dr. Berndt, a comment regarding his potential industry bias is necessary. The Court called for the appointment of an "independent" expert, and plaintiffs believe the Court wanted an expert as free from any possible bias as possible. The parties had a compressed time frame to select the "independent expert." When Dr. Berndt was contacted about the assignment by plaintiffs, he was informed of the nature of the case, and that the Court was looking for an independent expert to explain the distribution and pricing of certain drugs within the pharmaceutical industry, and to make observations with respect to the issue of whether methodologies could be utilized to prove plaintiffs' claims on a class-wide basis. Although he acknowledged that he had done some work for a few pharmaceutical companies, Dr. Berndt did not reveal that his affiliated consulting group, which did not appear on the M.I.T. website describing his qualifications, lists as clients many of the major pharmaceutical companies, including all but one of the Fast Track defendants.[3] And perhaps most importantly, Dr. Berndt did not reveal at anytime in the selection process that, in lieu of being a neutral or "independent," as to the issues in this case, he had served as an expert opposing the "but for methodology" for proving class-wide impact in the

[3] *See* http://www.analysisgroup.com/pa_antitrust.htm; *see also* www.analysisgroup.com/cl_health.htm, also listing defendants Aventis, Boehringer, GSF, Janssen, Johnson & Johnson, Ortho Biotech, and Pharmacia as clients.

Synthroid case.[4] In *Synthroid*, the Court rejected many of the same arguments made by defendants here, and specifically rejected Dr. Berndt's opposition to class certification. *Id*. at 300-01. Thus, Dr. Berndt has a history that, rather than qualifying him as an "independent" expert, augers in the opposite direction. Given his history and the clientele of his consulting group, Dr. Berndt is not "independent." This is stated without any disrespect toward Dr. Berndt, but plaintiffs believe these facts are important for the Court to consider. If fully aware of those facts, plaintiffs would have vigorously contested his qualifications as "independent" and would not have assented to his appointment.

Finally, although Dr. Berndt is not a lawyer, he did receive from the Court various cases dealing with class certification. In evaluating the existence of common questions, his report makes no reference to the fact that most of these defendants have previously agreed to class certification, in other cases in which the pricing of drugs, and their purchase by third-party payors and consumers, has been at issue – despite the "complexity of distribution" on all Rule 23 issues except manageability.[5] Further, Dr. Berndt makes no acknowledgement anywhere in his report of the standards courts have employed in "but for" or "yardstick" cases like *Synthroid*, *Brand Name*,[6] *Goda v. Abbott*,[7] *Cardizem*,[8] *Relafen*, *Lupron* and many others cited in Plaintiffs' Appendix A to their Reply Brief. To the extent Dr. Berndt raises questions as to Dr. Hartman's methodology, these cases reject similar arguments in the class certification context, and Dr. Berndt does not acknowledge or try to deal with such authorities.[9]

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[4] *In re Synthroid Mktg. Litig.*, 188 F.R.D. 295 (N.D. Ill. 1999).

[5] *See, e.g.*, *In re Buspirone Antitrust Litig.*, MDL 1413 (S.D.N.Y. 2003); *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231 (D. Del. 2002), *aff'd*, 391 F.3d 516 (3d Cir. 2004); *Rosemarie Ryan-House, et al. v. GlaxoSmithKline plc et al.*, C.A. No. 2:02cv442 (E.D. Va. July 28, 2004); *Nichols, et al. v. SmithKline Beecham Corp.*, C.A. No. 00-cv-6222 (E.D. Pa. Oct. 18, 2004); *In re Lorazepam & Clorazepate Antitrust Litig.*, 205 F.R.D. 369 (D.D.C. 2002); *In re Lupron® Mktg. & Sales Practices Litig.*, 345 F. Supp. 2d 135 (D. Mass. 2004); *In re Relafen Antitrust Litig.*, C.A. No. 01-cv-12239 (D. Mass. Nov. 24, 2004).

[6] *In re Brand Name Prescription Drugs Antitrust Litig.*, 1994 U.S. Dist. Lexis 16658 (N.D. Ill. Nov. 15, 1994).

[7] 1997 WL 156541 (D.C. Super. 1997).

[8] *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. 326, 345 (E.D. Mich. 2001).

[9] *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. 672 (S.D. Fla. 2004).

III. DR. BERNDT CONFIRMS THE UNIFORM USE OF AWP IN THE PART B MARKETPLACE

With respect to the Part B component of the physician-administered drug Class, plaintiffs have presented through allegations, evidence and a trial plan, the existence of common issues that predominate. Defendants feebly attempted to defeat certification of this Class by claiming that there was variability with respect to Part B reimbursement.[10]

As to Part B reimbursement, Dr. Berndt finds that in 1992 HCFA "adopted a uniform national payment system based on 100% of AWP" and in 1997, Congress amended the schedule to allow for payment at 95% of AWP. Berndt, ¶¶ 94-96. Thus, with respect to Part B, Dr. Berndt finds that for a variety of reasons AWP was the "***de facto***" ***benchmark***. *Id.* at ¶ 63. To the extent Dr. Berndt's report addresses Part B, it thus soundly rejects defendants' factual assertions, made through Young, that AWP was not the basis for reimbursement in this marketplace.

Dr. Berndt's only other relevant point as to the Part B Class is a complete rejection of Schering's contention that no incentive exists for generic manufacturers to market the spread. To the contrary, Dr. Berndt found that not only did such incentives exist, but spreads were in fact substantial and increasing over time as the AWP of generics either increased or remained flat, while ASP declined. *Id.* at ¶¶ 43-46.

Thus, to the extent it applies to the Part B Class, Dr. Berndt's report confirms the ability of plaintiffs to move forward on a class-wide basis.

IV. PHYSICIAN-ADMINISTERED DRUGS OUTSIDE OF PART B

Dr. Berndt does address, though not in great detail, the issue of common proofs with respect to physician-administered drugs.

To put his report in context of Rule 23, plaintiffs have identified the following common issues for this Class:

[10] *See, e.g.*, Young Decl., ¶¶ 169-72.

a. Defendants' communications leading to published AWPs.

b. Throughout the class period through the use of discounts, promotions, rebates, grants and other arrangements the actual price was far less.

c. Defendants' purpose in creating the spread was to increase market share by providing the physician with a profit.

d. The Third-Party Payors or other Class members reimbursed the Physician based on AWP.

e. It was foreseeable that reimbursement was based on AWP.

f. The creation of the spread in these circumstances was in violation of state law.

g. What the price would have been but for the unlawful acts of defendants.

Defendants' opposition focuses on items (d) and (g). As to item (d), defendants in their initial opposition attempted to show that physician-administered drugs are not reimbursed based upon AWP. When plaintiffs examined the actual contracts cited by Young to support this proposition, they were all in fact based upon AWP, and plaintiffs demonstrated this in reply.[11] Realizing they were in danger of losing this part of the Class, defendants, through Young, filed 98 pages in sur-reply, with 20 binders.

Almost all of this material is directed at physician-administered drugs outside Part B, Dr. Berndt cites to it repeatedly.[12] As demonstrated in Plaintiffs' Motion to Strike Young's Surreply,[13] this material is misleading, unreliable and so false as to be sanctionable. Dr. Berndt has been misled in many respects by Young, and his report is thus tainted by Young's conduct. Despite Young's misconduct, Dr. Berndt concludes that "the record is unsettled to date" as to whether payments to physicians in the physician-administered arena are based on AWP or are part of a "negotiated fee schedule." Berndt, ¶ 98. As demonstrated in plaintiffs' motion to

[11] Hartman Reply Decl. ("HRD") at ¶ 34(c); *see also* p. 46, App. 1k.

[12] *See*, *e.g.*, Berndt at footnote 144, citing to Young's Sur-reply and his appendices.

[13] Filed on March 10, 2005.

strike, such contracts are typically based upon AWP and are easily identifiable in the claims process.

In an effort to keep the record "unsettled," defendants did not place before Dr. Berndt documents they subpoenaed that further demonstrate the error in Young's assertions that physicians are not reimbursed based upon AWP, or that reimbursement is part of a negotiated fee schedule. For example, Premera Blue Cross not only specifies that its reimbursement is expressly based upon AWP, it also specifies different percentages of AWP based on the type of physician-administered drug.[14] Both Caremark and Medco specify in their contracts as a basis for reimbursement for physician-administered drugs a specific percentage of AWP for each type of injectible or specialty drug.[15] Thus, to the extent Dr. Berndt finds this issue to be "unsettled," his report does not further the Rule 23 analysis on this issue, and the true record free of Young's misleading submission indicates that AWP is the basis for reimbursement in the non-Part B physician-administered marketplace.

Not only did Dr. Berndt not accept Young's claim that payments to physicians are based upon a "negotiated schedule," Dr. Berndt also agrees with Dr. Hartman that physicians have incentives to play the spread game, and that the opportunity to do so exists.[16] Thus, Dr. Berndt finds plausible the existence of common issues with respect to use of the spread in this market.

On sur-reply Young, spends a great deal of time trying to claim that because J-Codes are used in the reimbursement process for physician-administered drugs it is impossible to tie these

[14] PBC 00200 (106.3% of AWP for injectible drugs on Plan's injectible drug list; 95.7% AWP for immunizations), attached to Rebuttal Declaration of Raymond Hartman in Response to the Sur-Reply Declaration of Young ("Hartman Rebuttal Decl.") at Exhibit E.

[15] PBC 00215-16 (Medco contract identifying, for example, Intron A reimbursed at AWP – 18.50%; Procrit at AWP – 17.50%; Remicade at AWP – 18.50%; Zoladex at AWP-18.50%. *See* Caremark Agreement at PBC 00239-40, similar discounts using AWP as the benchmark) attached as Exhibit I to Hartman Rebuttal Decl.

[16] *See, e.g.*, Berndt, ¶ 198 (Because of J-Code reimbursement, "it has been difficult for healthcare organizations to monitor and observe the utilization and pricing trends underlying their expenditures on physician-administered drugs."); *Id.* at ¶ 199 ("[I]ssues of pricing transparency become an order of magnitude larger" in physician-administered context. "This creates opportunities for mischief and abuse that are very different form and much more obvious than in the case of self-administered drugs."); *Id.* at ¶ 200 (discussing a "system lacking checks and balances and inviting abuse"); *Id.* at ¶ 228 ("... the quality of general information concerning actual prices for physician-administered serves are likely to have been very poor").

transactions to AWP. To the extent Dr. Berndt believes that this issue makes class certification difficult, he is wrong. Dr. Berndt admits that he has not examined any of the actual databases to see how difficult such a task will be. Dr. Hartman has done so and documents how contracts in this area, even if using a J-Code, can be traced to an AWP.[17] Responding to Young's claims, Dr. Berndt recognized in some circumstances the crosswalk between J-Codes and NDC's will be "very simple," in other cases more complex. Berndt, ¶ 197. There is certainly nothing in his report that would agree with Young's assertions that certifying this Class is impossible due to the J-Code issue. As recent opinions have noted, *IPO* for example, the existence of difficult tasks down the road does not negate the need to certify a class.

Finally, as Dr. Hartman has explained, Young's analysis is again misleading. Examining documents from the third-party payors reveals (1) reliance upon NDC-specific AWPs within J-Codes in contracts is common and routine, (2) procedures have been developed that allow providers to crosswalk between NDCs and J-Codes,[18] and (3) the use of J-Codes does not prevent the determination of aggregate damages for this class.[19]

In summary, as to the common issues he does address, Dr. Berndt does not find plaintiffs' evidence and proposed methodology to be seriously flawed or so implausible as to the certification of the proposed non-Part B physician-administered Class.

V. SELF-ADMINISTERED DRUGS

Most of Dr. Berndt's report deals with self-administered drugs. In order for his observations to be useful, they need to be placed in the context of how plaintiffs plan to prove both their RICO claims and consumer claims for self-administered drugs.

[17] *See* Hartman Rebuttal Decl. at Section II; HRD at pp. 46-48, and Attachment D.3 regarding Zoldex.

[18] Hartman Rebuttal Decl. at pp. 10-17.

[19] *Id*. at pp. 17-22.

A. Brand Name Drugs

First, plaintiffs will establish through common proof that AWP was the basis for reimbursement for each Class member. The Class definition is confined to those who by contract used AWP as a pricing standard. Defendants' own documents prove beyond any doubt that AWP was the "industry standard," and that "payers use AWP as a basis for reimbursing retail pharmacies," to such an extent that AWP is the "***anchor***" for reimbursement. In defendants' own words, used in their own documents, any increases in AWP will increase the spread and the amount paid by Class members.[20] Dr. Berndt completely ignores these documents. He thus takes no measure of defendants' own admissions as to the class-wide impact of manipulating the spread. *Id*. The fact remains that they are a strong component of the common evidence and issues that plaintiffs will present at trial. To simply ignore what defendants themselves were saying at the time undermines the usefulness of Dr. Berndt's observations with respect to how issues will be tried based upon common proof of the scheme for self-administered drugs.

Second, plaintiffs offered to prove this industry standard through the introduction of contracts at every level of the distribution chain that uniformly use AWP as the basis for payment. An examination of the 1,200-plus contracts produced in the litigation reveals that virtually ***every*** contract utilizes AWP as a basis for reimbursement.[21] Indeed, senior industry executives recently testified before Congress that AWP was "codified" for use in the public sector and "by contract" in the private sector.[22] This uniformity, or "codification," of the use of AWP by each Class is supported by deposition testimony from health plans, their consultants and PBMs as to the standardized use of AWP and its perceived reliability as a negotiating

[20] Berman Reply Declaration ("BRD") filed in connection with Plaintiffs' Reply Memorandum in Support of Class Certification. Ex. 1 (AZ 0565612).

[21] *See* HRD at ¶ 22, p. 26 (referring to an analysis of more than a thousand contracts produced in the case).

[22] *See* BRD Ex. 4 (Statement of Edward Stratemeier before U.S. House Subcommittee dated December 7, 2004).

benchmark.[23] This evidence comports with Dr. Hartman's opinion that AWP is the "single publicly available list price that is the basis for the preponderance of all negotiations."

Dr. Berndt appears to also ignore all of this common proof. Nonetheless, Dr. Berndt agrees with plaintiffs in this regard:

> In this way, even though industry observers and academics have quipped that AWP stands for "Ain't What's Paid" rather than "Average Wholesale Price," it is ***nonetheless the case that AWP has served as a reference or focal point, an industry standard for baseline reimbursement, and as such a fictional benchmark price from which discounts are frequently specified directly or indirectly***. Hence, as Plaintiffs' Expert Dr. Raymond Hartman has written, "AWP is interpreted by the industry as a measure of the underlying structure of drug prices," and "The AWP, or its formulaic equivalent the WAC (Wholesale acquisition cost), is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs."[24]

In the same vein, Dr. Berndt finds that "since AWP was publicly known, it served as a convenient focal point metric for contractually specifying various reimbursements, and for efficiently adjudicating pharmacy transactions electronically."[25]

While defendants, and Young in particular, spent hundreds of pages claiming that AWP is not the reimbursement benchmark, Dr. Berndt disagrees. Thus, this method of proving common issues is fully supported by Dr. Berndt.

Third, plaintiffs can prove through deposition testimony, contracts and expert opinion, that because AWP is the "starting point" for prescription drug reimbursement," it follows that if "the starting point for prescription drug reimbursement is artificially inflated, the resulting reimbursement rates paid are also artificially inflated."[26] ***After acknowledging that AWP is the benchmark or "focal point metric," Dr. Berndt never really addresses this critical issue,***

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[23] *See* App. 1(a) and App. 1(b) (summarizing deposition testimony regarding the reliability of AWP and its use as a reimbursement benchmark). *See also* BRD Ex. 5 (Testimony of David Joyner, Executive Vice President of Caremark, one of the major PBMs. "I know of no other pricing source that is as comprehensive and accepted across the industry as AWP" cited in HRD at ¶ 25(a), p. 31).

[24] Berndt, ¶ 16 (emphasis added).

[25] *Id.* at ¶ 23.

[26] HRD at ¶ 3(d), p. 4, ¶ 15(a)-(d), ¶ 25(d), p. 31.

namely if in fact the starting point of reimbursement is inflated, it is not unreasonable to conclude and model the effect of that inflation on Class members. Numerous cases have recognized exactly such a proposition, and Dr. Berndt does not address the economic rationale set forth in these cases.[27]

Plaintiffs will also introduce expert testimony based upon economic analysis that, although some Class members knew that AWP was greater than acquisition cost, "no one knew that the AWPs were grossly inflated" relative to such costs or that defendants were purposefully marketing the spread.[28] On this issue, Dr. Berndt distinguishes between brand name drugs and generic drugs when addressing this issue of class "knowledge." As for brand name drugs, he notes the publication of OIG reports observing a difference of 10-20% between AWP and acquisition cost. Berndt, ¶ 63. Thus, Dr. Berndt's report fits nicely with Dr. Hartman's yardstick approach that finds that market knowledge as to the range of discounts on brand name drugs created a ***narrow*** band of contractual arrangements of 14%-18% despite Dr. Berndt's views on PBM competitiveness. Dr. Berndt does not find otherwise, and thus plaintiffs can proceed by class-wide proof that the market did not expect discounts on brand name drugs to vastly exceed this range.

As to class-wide knowledge of discounts on generic drugs, Dr. Berndt strays from his assignment of explaining the market to pure advocacy and merits opinion, when he states "I conclude, therefore, the fact that AWP very substantially overstate pharmacies' actual acquisition cost for generic self-administered drugs has long been publicly available." Berndt, ¶ 73. Not only is this a merits opinion, Dr. Berndt fails to explain if information were really public why the thousands of contracts Dr. Hartman references in his report do not reflect such knowledge. Further, and perhaps more importantly, the studies Dr. Berndt relies upon show

[27] *See, e.g., In re Cardizem CD Antitrust Litig.*, 200 F.R.D. at 345; *In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. at 699.

[28] HRD at ¶¶ 50-57, 60, pp. 63-68, 70. *See also* App. 1(d) (summarizing testimony of Class members' lack of knowledge of actual spreads). *See also* App. 1(f) (lack of knowledge of extent of rebates and discounts and other offsets).

discounts of 45%, 37%, 57%, and 42% on generic drugs. *Id*. at ¶¶ 70-71. Nowhere does Dr. Berndt cite to class knowledge of the spreads identified by Dr. Hartman of 250% to 3,878%.[29] Again, Dr. Berndt's failure to identify any reports of knowledge of this type of disparity in the marketplace simply confirms the existence of common issues and proof as to the lack of market knowledge of the scheme. Finally, Dr. Berndt repeatedly states that there was knowledge of the fact that AWP and ASP were different. And, he observes that the difference between WAC and AWP is not "nefarious." Plaintiffs do not contest otherwise, but this is not what this case is about. ***What Dr. Berndt never addresses as to public knowledge is (1) the lack of knowledge of the purposeful use of marketing the spread to reward providers, PBMs, and retailers at the expense of the Class, and (2) the real magnitude of the secret spreads***.

Plaintiffs will also prove through economic analysis, in addition to the contract analysis mentioned above, that AWP and reimbursement are commonly linked. Dr. Hartman found that there is an "obvious demonstrable positive relationship between reimbursement rates and AWP," for brand name,[30] generic[31] and physician-administered drugs,[32] and provides a method for doing so on a class-wide basis. Dr. Berndt does not disagree anywhere with this demonstrable relationship. Thus, this element of common proof remains untouched by Dr. Berndt.

As an additional method of common proof, Dr. Hartman will establish a benchmark or yardstick beyond which the AWP was inflated. This is not a subjective standard as defendants portray it. Rather, that benchmark will be based on evidence and techniques relied upon by economists (which Mr. Young, defendants' principal expert is not) and is an objective standard

[29] Hartman Table 2.C.

[30] HRD at ¶ 23, pp. 27-28. Dr. Hartman analyzed actual claims data to determine the frequency claims were paid by Harvard Pilgrim Health Care with reference to AWP. Among the sample looking at branded drugs, 96-98% were paid by reference to AWP. For generics, 52.8% were paid with reference to AWP. HRD at ¶ 23(c), p. 27. Hartman then demonstrates how this can be done for other Class members where he achieved similar results. HRD at ¶ 23(h)-(i), pp. 29-30.

[31] HRD at ¶ 33(d), pp. 39-41; ¶ 34(b), pp. 44-46.

[32] HRD at ¶ 34(c), pp. 46-47, Attachment D. Dr. Hartman describes how reimbursements for physician-administered drugs track the AWP, and using Zoladex as an example, and observes the same pattern of overcharge as in the government action involving Lupron. *See also* HRD at ¶¶ 34-35, pp. 47-48, applying a regression analysis and finding a statistically significant relationship between AWP and reimbursement.

based on quantitative analysis.[33] Purchases at prices above that benchmark establish impact for all members of the Class purchasing that specific drug at a price deemed to be inflated by Dr. Hartman's model. Where behavior artificially raises the price of a product that is used throughout an industry, courts have allowed proof of liability and damage on a class-wide basis.

The crux of Dr. Hartman's yardstick is that the market reasonably expected that AWP was a meaningful signal as to actual transaction prices. Dr. Berndt agreed finding that AWP "is interpreted by industry as the signal for the underlying structure of list and transaction prices for almost all drugs." Berndt, ¶ 16. He thus endorses the exact yardstick Dr. Hartman uses, and finds the market "plausibly relied" on AWP. *Id.* at ¶ 24. Dr. Berndt thus supports Hartman's analysis of the yardstick approach, a measure defendants vigorously contested, though he opines Dr. Hartman needs to address a variety of issues in preparing a final model.[34]

As noted in plaintiffs' reply, defendants' position regarding the need for millions of individual inquiries also ignores a basic theory of economics of "revealed preferences" that suggests that economic agents indicate what information they relied upon by their behavior. In this case, the revealed preferences result in a cluster of contracts at AWP – 14% to 18%, which reveals class-wide expectations that the spread between AWP and AAC was AWP - 20% at the most.[35] Dr. Hartman's analysis demonstrates that all members of the Class, even those with "bargaining power," continued to pay within the range of AWP – 14% to 18%, which in turn, as a matter of economic analysis, indicates a class-wide absence of knowledge of the AWP scheme.[36] Dr. Berndt was aware of Dr. Hartman's contention on these points and on the theory of "revealed preferences" and expresses no disagreement. Again this leaves untouched another method of common proof.

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[33] HRD at ¶ 45(b), p. 58 (method follows standard economic methods). *See also* Section V at pp. 60-72.

[34] *Id*. at ¶ 17. His critique of the yardstick is addressed in Section VI, *infra*.

[35] HRD at ¶¶ 41, 50-53, pp. 51-53, 63-64.

[36] HRD at ¶¶ 50-53, pp. 63-64. *See also* Young Decl., ¶¶ 134, 138 (confirming range of discounts).

Thus, when one looks at the common proof needed to establish plaintiffs' case on brand name drugs in this market, Dr. Berndt's report either does not address such methods of proof, or agrees in large measure with Dr. Hartman.

B. Generic/Multisource Self-Administered Drugs: Dr. Berndt Agrees that the Scheme Exits in the Generic Market

Dr. Berndt's discussion of industry reliance upon AWP for single-source brand-name self-administered drugs describes a similar industry reliance upon AWP for generic multisource self-administered drugs. In this regard, Dr. Berndt relies heavily on longtime defense expert Professor Kolassa. According to Professor Kolassa,[37] as quoted by Dr. Berndt:

- "This use of the AWP is even more pronounced with generic drugs." Berndt, ¶ 43.
- "It is also common for the AWP of a generic product to remain stable while the actual selling price declines, leading to differences between ex-factory prices [*i.e.*, ASPs] and AWP ranging from 20% to 1,168%." *Id.* at ¶¶ 44-45.
- As a result, "[m]any generic companies have taken advantage of this use of AWP by inflating their published AWPs substantially. For instance, in 1989 Geneva Generics increased some AWPs by as much as 1000% while decreasing their selling prices." *Id.* at ¶ 43.
- Professor Kolassa reports prices for two non-steroidal anti-inflammatory drugs available in brand name and generic versions. He finds the pricing behavior alleged in this matter: "This tactic, then, [of increasing the AWP – ASP spread] allows retailers to acquire a drug at a low cost, less than $5.00 per hundred, yet rely on a published AWP as high as $15.00 or more for their own pricing. It is not uncommon that the $25.00 retail price for a generic drug renders a gross profit well above $20.00 for the retailer." *Id.* at ¶ 44.
- Professor Kolassa concludes, as did Dr. Hartman, that an increased spread between AWP and the acquisition cost of the generic drug was used to move market share. Specifically, "[i]t is obvious that AWP is not an accurate measure of the prices manufacturers charge. It must also be noted that not all generic products will be

[37] Though Dr. Berndt cites extensively to Kolassa, he neglects to mention that Kolassa works for the pharmaceutical industry ***and is an expert for defendants in this case***. So we have Dr. Berndt, employed frequently by the industry, citing to an industry expert in this case. Thus, it is even more striking that both experts agree with plaintiffs' allegations.

> priced similarly. Some, in fact, use the more traditional method of a 20% markup to reach an AWP. This can be a handicap for generic companies choosing this method because retailers often use the AWP as the starting point for many pricing decisions and ***an artificially high AWP provides the retailer with greater profits.***" *Id.* at ¶ 45 (emphasis added).

Thus, Dr. Berndt confirms that common proof as to the existence of the scheme in the generic/multi-source marketplace is plausible.

Having confirmed the existence of substantial spreads in the generic marketplace, Dr. Berndt then sheds any pretense of independence and offers an opinion that third-party payors do not care about these spreads. He opines, without citation to any survey, evidence[38] or documents, that it is "understood that third-party payors" have allowed these spreads because they save money on generic drugs. *Id*. at ¶ 52. Frankly, such an opinion is not only improper at this stage, it is shockingly unsupported. To even suggest such a conclusion, Dr. Berndt would need evidence that third-party payors had knowledge of the spreads at issue here, 200%-3,700% or more, and he has no such evidence.

Next, again unabashedly delving into the merits, Dr. Berndt attempts to argue that any additional margin retained by retailers as a result of the spreads on generics covers higher dispensing fees for generics. Again, this is a pure merits opinion and a speculative one at that. Dr. Berndt bases this conclusion upon a survey of Medicaid dispensing fees, which certainly is not representative. Medicaid transactions are not included in the proposed Class. Furthermore, the underpayment of dispensing fees is usually at most a dollar or two, whereas the alleged spreads are much larger. Indeed, in the example presented by Professor Kolassa involving non-steroidal anti-inflammatory drugs (*see* p. 16, *infra*), the gross profit earned by pharmacies as a result of the spread is $20, which vastly outweighs any difference in dispensing fees ($1 - $2). Finally, Dr. Berndt's excuse for why this extraordinary spread is "unimportant" to third-party payors is not germane to the issues presented by Rule 23.

[38] His only evidence is Navarro's opinion regarding two companies. Berndt, ¶ 53. From this limited basis, Dr. Berndt forms a conclusion as to a class of 20,000 third-party payors.

C. PBM Competition

A great deal of Dr. Berndt's report, and his major area of disagreement with Dr. Hartman, concerns the degree of competition in the PBM market and not the issue of AWP inflation. Dr. Berndt, again delving into the merits, concludes that the existence of competition among PBMs is critical to plaintiffs' theory, though competition has little to do with the AWP inflation scheme that is at the core of this case. He then finds that PBMs are competitive and concludes that this undermines plaintiffs' assumption of class-wide injury and damages.[39]

Dr. Berndt's opinion on competition among PBMs does not change the landscape on class certification. First, this is again his weighing of the evidence. Second, and more importantly, competition among PBMs has little to do with plaintiffs' claims or the issues presented by the motion for class certification. The claims involving the PBMs arise from their ability to benefit by retaining part of the spread. Proof in this regard will come from the PBM's transactional records demonstrating how they make money off the spread. Thus, though Dr. Berndt's opinions as to competition might be interesting to academics, they have little to do with the proofs that will be offered at trial. In this regard, a February 15, 2005 article in the WALL STREET JOURNAL confirms plaintiffs' underlying theories and highlights the type of common proof that will be introduced at trial.[40] The subject of the article is GM and Medco's agreement that GM employees can only obtain refills through Medco's mail order and not at a retail store. The article notes:

> For example, 90 ranitidine pills usually cost pharmacies about $7. At retail, customers can pay $22. Medco's mail-order price to GM is $181.22. Medco can show its customers a great savings because the list price, called the average wholesale price, quotes ranitidine at about $264 for 90 pills. Medco declined to comment on specific prices on its Web site.

[39] Nowhere in the AMCC (now the Second Amended Complaint (SAC") is there any mention of a "lack of competition" as a predicate to plaintiffs' claim). *See* SAC ¶¶ 647-59 (describing PBM role).

[40] The Court ordered the parties submit a brief with no exhibits, opinions or other materials so this article is not attached.

In this example, if Medco made 2% on each transaction, and the 2% is based upon AWP, Medco comes out with more profit irrespective of competition with other PBMs. The foregoing is the type of evidence cited in the AMCC and which will form the basis of plaintiffs' proof at trial. Dr. Berndt's foray into competition among PBMs offers no insight into whether plaintiffs can proceed by way of class-wide proof in regard to the issue of AWP inflation.

Finally, and as touched upon *supra*, PBMs' ***common*** use of AWP as a pricing benchmark demonstrates that the pricing base is tainted for ***all*** transactions, no matter how robustly Dr. Berndt views competition in the PBM sphere. Thus, the PBMs' common use of the tainted AWP minimum baseline affords common proof of damage on a class-wide basis. *See*, *e.g.*, *In re Commercial Tissue Prods Antitrust Litig.*, 183 F.R.D. 589, 595 (N.D. Fla. 1998) ("class plaintiffs may succeed in proving classwide impact by showing that the minimum baseline ... was artificially inflated....").

VI. THE BERNDT REPORT DOES NOT FIND DR. HARTMAN'S METHODOLOGY TO BE OUTSIDE THE SCOPE OF RECOGNIZED ECONOMIC TECHNIQUES

Defendants' opposition is replete with attacks on Dr. Hartman's methodology, calling it at times "junk science," "unreliable" and a host of other adjectives. Defendants moved to strike Dr. Hartman's testimony in this regard, and Dr. Berndt received this briefing. None of those criticisms are adopted by Dr. Berndt, who implicitly recognizes that employing a yardstick methodology and/or regression analysis is not inappropriate or unusual technique for demonstrating class-wide impact. Although Dr. Berndt raises issues that should be and will be addressed by Dr. Hartman when delivering a final liability report, they do not provide a basis for denying certification.

A. Measurement of Class-wide Injury

The model for calculating aggregate damages presented by Dr. Hartman and critiqued by Dr. Berndt works as follows: While this industry is complex, the implementation of the requisite formulaic methodology to calculate aggregate class-wide damages is really no different than

those supporting certification in other drug pricing cases[41] or those implemented in actions involving other complex industries.[42]

At this stage of the litigation, plaintiffs are required to plausibly outline a method for proving aggregate class-wide injury. To that end, for any given drug (that is, for all NDCs of that molecule), injury will be determined by three factors:

(a) The extent to which the measured spread is above the yardstick spread, where for our purposes, the yardsticks are to be estimated to reflect aggregate average expectations. Deviation between the actual and yardstick spread measures the extent to which the AWP is artificially inflated above the transaction price (ASP) for which it is the "plausible" (using Dr. Berndt's term (Berndt, ¶ 24)) signal. Taking account of that deviation will provide the "but-for" AWP, from which reimbursements are and will be calculated.

(b) The extent to which the percentage reduction off AWP in calculating the reimbursement rate changes in the but-for world. Specifically, as Dr. Berndt admits (*id*. at ¶ 27), reimbursement rates are driven by "common contracting terms and common algorithmic formulas" such that reimbursement rates are AWP – x%. In the but-for world, it is possible that the x% will be different; that difference needs to be analyzed and calculated.

(c) The number of units of the specific drugs (NDCs) subject to the AWP scheme.

Calculation of the actual spreads and unit sales is quite straightforward for all NDCs of all drugs.

(a) Manufacturer invoice, rebate and accounting data will allow for sufficiently accurate measures of the ASPs and the quantity of each NDC sold.

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[41] *See, e.g., In re Terazosin Hydrochloride Antitrust Litig.*, 220 F.R.D. at 698-99; *In re Cardizem CD Antitrust Litig.*, 200 F.R.D. at 345; *In re Brand Name Prescription Drug Litig.*, 1994 U.S. Dist. Lexis 16658, at *11-12 (N.D. Ill. Nov. 18, 1994).

[42] *See, e.g., In re Microcrystalline Cellulose Antitrust Litig.*, 191 F.R.D. 472, 484-85 (W.D. Pa. 1999); *In re Commercial Tissue Prods.*, 183 F.R.D. at 589, 595 (N.D. Fla. 1998); *In re NASDAQ Market-Makers Antitrust Litig.*, 169 F.R.D. 493, 522 (S.D.N.Y. 1996); *In re Catfish Antitrust Litig.*, 826 F. Supp. 1019, 1043-44 (N.D. Miss. 1993).

(b) Publicly available data (*Red Book* and/or *First DataBank*) will provide the requisite AWPs.

Though he offers criticisms, Dr. Berndt does not find this method of proceeding outside the range of normal economic analysis.

B. Addressing the Berndt Critique

The crux of Dr. Berndt's "preliminary" observations on Dr. Hartman's approach, made without his analyzing any of the defendants' data[43] as Dr. Hartman has done, is to point out a variety of factors or refinements Dr. Berndt believes that Dr. Hartman will have to consider before any yardstick approach is finalized. Again, Dr. Berndt does not opine that Dr. Hartman's approach is illogical, incorrect or inadmissible, or that at the appropriate time he will not be able to consider these factors.

Plaintiffs agree that calculation of yardstick spreads must be done carefully and that the yardsticks need to be refined based upon a full record. Dr. Hartman stated as much throughout his opinion. However, the fact that care must be used in no way implies that yardsticks cannot be calculated. Information for calculation of the yardstick spreads is certainly available. The OIG studies to which Dr. Hartman refers as a basis for assessing a yardstick is just one reference. Dr. Berndt refers to analogous OIG and CBO information for generic drugs spreads and how those spreads changed over time. He provides in his Tables 2 and 3 additional information on spreads and discounts for brand name drugs over 1995-2000. He further suggests that it might be useful to examine whether yardstick spreads should be differentiated by pharmacy class of trade, rural versus urban pharmacies and by state. He extends the categories by which the yardsticks could be disaggregated.

The point is that yardsticks can be calculated and can be used to demonstrate class-wide impact, and Dr. Berndt does not conclude otherwise; indeed, such an approach has been

[43] Dr. Berndt admits he has not analyzed any of defendants' databases.

routinely approved by courts. While those yardsticks might be differentiated somewhat by sub-class and by time where appropriate as Dr. Berndt suggests, at this stage of the litigation plaintiffs are not required to calculate impact or damages for each homogeneous sub-class or for each Class member in each year of the damage period. That analysis is to be implemented in final liability and damage reports. At that point many of the variations addressed by Dr. Berndt would be appropriately analyzed and incorporated where needed.

Thus, unlike the attacks made by Young and other defense experts, Dr. Hartman and Dr. Berndt largely agree on the use of economics to study impact on an aggregate level and any disagreement revolves around refinement and not the use of yardsticks, benchmarks or regression analysis.

C. Berndt's "Other Factors" for AWP Inflation Are Misplaced

One of Dr. Berndt's critiques of Dr. Hartman's "but for" methodology is his alleged failure to account for other factors that may be the basis for a manufacturer's decision on how to set AWP, ASP, and the spread. Berndt, ¶ 214. Dr. Berndt pulls these factors from "literature," and not from evidence in this case. However, in the context of common proof, plaintiffs will present evidence that marketing the spread was part of a scheme. Such evidence is cited in the complaint and outlined in plaintiffs' submission on the class motion.[44] Plaintiffs' illustrative materials, at oral argument, described by way of example a Johnson & Johnson computer program designed to show doctors how to make money off the spread. Such evidence will be common to each Class member will be part of the common proof, and has nothing to do with any of the factors in the "literature" cited by Dr. Berndt. Indeed, defendants themselves did not raise most of the factors identified by Dr. Berndt as the basis for the spread. Each defendant had an opportunity to put in testimony from their own employees that, for example, "initial FDA priority designation" (*id.* at ¶ 214) was the reason for the spread, but they did not do so.

[44] *See e.g.*, SAC ¶¶ 236-49 (Astrazeneca); ¶¶ 331-48 (BMS); ¶¶ 382-415 (GSK); ¶¶ 438-41 (J&J); and ¶¶ 482-94 (Schering). In coming up with his list of factors, Dr. Berndt completely ignores these allegations and the evidence.

Dr. Berndt's volunteering of such factors speaks of his background in representing the industry, but in any event, to the extent defendants assert such factors, the Class will be united in showing these factors were not a factor in creating the spread. But even more importantly, to the extent defendants created a spread that varied beyond market expectations for whatsoever reason, the use of an inflated AWP was a deceptive practice. Again nothing in Dr. Berndt's "factor" comments will defeat common proof.

VII. CONCLUSION

To the extent Dr. Berndt's "initial observations" are relevant they support the certification of the proposed classes.

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CERTIFICATE OF SERVICE

I hereby certify that I, Steve W. Berman, an attorney, caused a true and correct copy of the foregoing, **PLAINTIFFS' MEMORANDUM REGARDING THE BERNDT REPORT** to be delivered to all counsel of record by electronic service pursuant to Paragraph 11 of the Case Management Order No. 2, by sending on March 10, 2005, a copy to Verilaw Technologies for Posting and notification to all parties

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